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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,297	11/26/2003	Raymond E. Conrow	2178 (3010-006-01)	5552
33432	7590	04/13/2005	EXAMINER	
KILYK & BOWERSOX, P.L.L.C. 53 A EAST LEE STREET WARRENTON, VA 20186			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/723,297

Applicant(s)

CONROW ET AL.

Examiner

Taofiq A. Solola

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: ____. |

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Claims 1-29 are pending in this application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility.

Under US patent practice the process of making a compound is not a utility, the compound must have an asserted or a well-established utility. In the instant process, the specification on page 1, lines 15-16, discloses 1-(aminoalkyl)indazoles as useful for treating CNS diseases. On page 21, the specification shows compounds 9 and 10, [1-(aminoalkyl)indazoles], which are made in the instant invention. Therefore, compounds 9 and 10 are deemed to have utility under 35 USC 101. Compounds 9 and 10 are made from compound 8, a sulfonic ester. Therefore, compound 8 is deemed to have utility under 35 USC 101, as being used to make medicinal compounds 9 and 10.

However, the instant claims are drawn to making "an indazole". While there are many known indazole compounds not all of them and their utilities are disclosed in the specification. By adding a generic formula embracing compounds 8-10 as the product being made to claims 1-29 the rejection would be overcome. Alternatively, applicant may identify in the claims all the indazole(s) being made, which must have support in the specification, so as to enable the Examiner determine if such compounds have asserted or well-established utilities.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "indazole", "aromatic aldehyde", "reducing agent", "sulfonyl halide", "anhydride", "metal azide" "catalyst", "organic solvent" and "hydrogen source" are not defined in the specification so as to determine the structures of compounds that are included and/or excluded by the terms. Therefore, the specification lacks adequate support for claims 1-29.

The specification must set forth any definition explicitly with reasonable clarity, precision and deliberateness, *Teflex Inc. v. Ficos North Ame. Corp.*, 63 USPQ2d 1374 1381 (Fed Cir, 2001). Applicant must show possession of the invention by describing it with all the claimed limitations. *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). By adding the specific compound names and/or add generic formulae which embrace applicant's reagent compounds, having support in the specification, the rejection would be overcome.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons set forth above under 35 USC first paragraph claims 1-29 are indefinite.

Claims 1-29 are written in functional language and therefore, broader than the enabling disclosure. For example, the claims recite "reacting", "nitrosating", etc. The claims must recite how one of ordinary skill in the art would perform the "reacting" or "nitrosating". The claims must recite the reagents, the reaction times, pH, and reaction conditions that are applicable in the steps. Applicant may not claim all processes of "reacting" or "nitrosating", that may be applicable in the instant invention. Applicant must claim only the processes of performing the "reacting" or "nitrosating" that embody applicant's invention. Under US patent law, a process claim must recite "how" the process is performed not "what" is done as in the instant claims. The structure of the product, indazole, is derived, in part, directly from the aldehyde starting compound therefore, only a specific aldehyde having a phenyl ring with the appropriate specific substituents can be used in the instantly claimed process not any aromatic aldehyde. Claiming all known aromatic aldehydes, reducing agents, catalysts, hydrogen sources, anhydrides, metal azides or organic solvents have the same utility (applicable in the instant process) is not believable. See MPEP 2107. According to the specification only specific reducing agent, catalyst, hydrogen source, anhydride, metal azide and organic solvent are applicable in the instant.

A claim must stand alone to define the inventions, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27

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USPQ 2d 1608, BdPatApp & Inter. (1993). In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

April 7, 2005